



Health Care Compliance Association  
Enforcement and Compliance Conference 2018

## Anatomy of a Corporate Integrity Agreement

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## Background on CIAs

- **OIG enters into CIAs in connection with the settlement of health care fraud cases**
  - False Claims Act (FCA)
  - Civil Monetary Penalties Law (CMPL)
- **CIA in exchange for OIG's release of its permissive exclusion authority**
  - 1128(b)(7) (fraud, kickbacks and other prohibited activities)



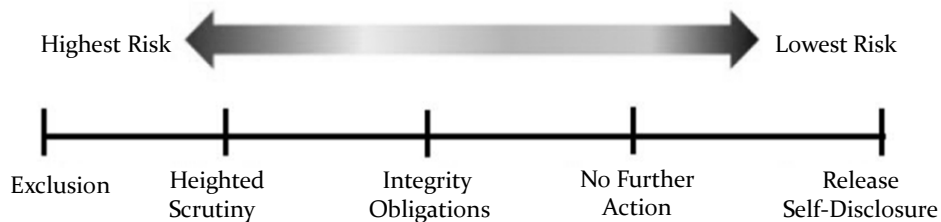


## Section 1128(b)(7) Criteria

- Criteria for Implementing Section 1128(b)(7) Exclusion Authority, issued April 18, 2016
- Resolution of exclusion authority is based on assessment of future risk to the FHCPs.
- “Risk spectrum” from low to high risk based on: (1) nature and circumstances of conduct; (2) conduct during government investigation; (3) significant ameliorative efforts; and (4) history of compliance
- Highest risk will result in exclusion; below highest risk, OIG may require integrity obligations or take no further action



## Risk Spectrum





## OIG's Fraud Risk Indicator

- OIG announced that in October 2018, it will begin publishing a list of individuals and entities it considers to pose a high-risk of healthcare fraud.
- These high-risk providers have refused to enter into corporate integrity agreements.
- Prior to the publication of this list, the provider and beneficiary community has been unable to know whether a settling entity belonged on the high-risk end of the spectrum—having refused to enter a CIA—or on the opposite end of the spectrum—having been determined by OIG to be low risk.
- The list provides transparency and information. It is not intended to change the manner in which providers operate.



## Background on CIAs

There are benefits to operating under a corporate integrity agreement:

- Cultural change
- Mandated structure
- Formal reporting process
- Compliance Officer's heightened standing
- Increased resources
- Organizational interest in corporate compliance





## Background on CIAs

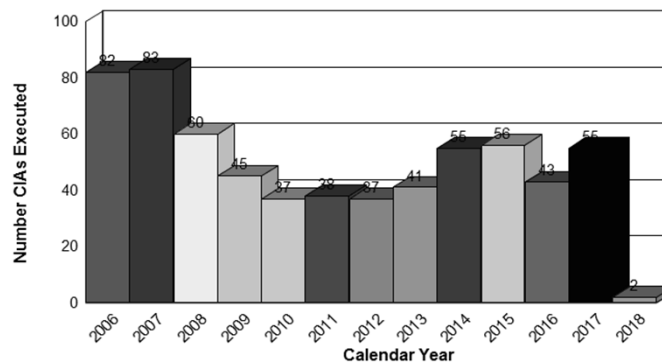
**What a CIA is:** an agreement in which the provider agrees to implement the foundational elements of an effective compliance program and to comply with other requirements.

**What a CIA is not:** a mechanism through which all fraud may be detected or prevented.

- The CIA lays out what a compliance program must include. Providers may do more, but certainly should not do less.
- Examples of compliance obligations that go beyond standard CIA requirements:
  - Refined use of analytics (public and internal data) to assess risk
  - Survey instruments
  - Connecting compensation and compliance
  - Engaging all areas of the business in the compliance process

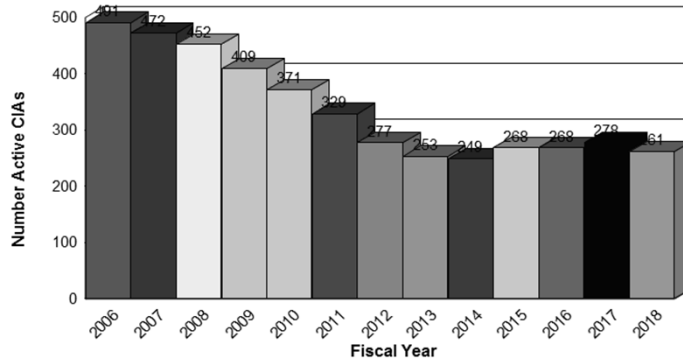


## Number of New CIAs

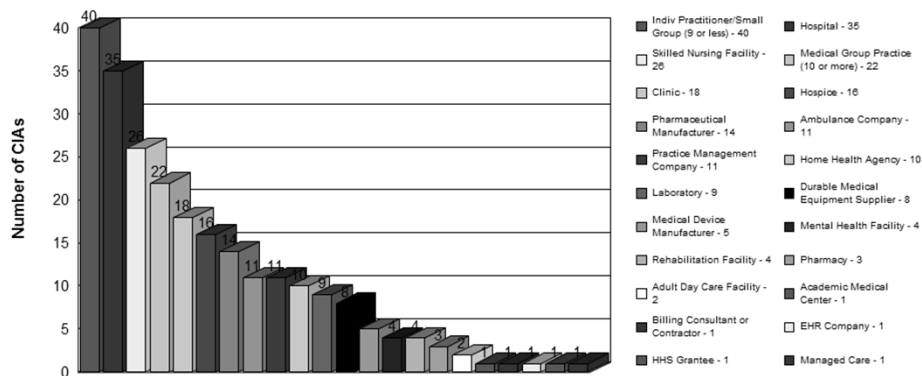




# Number of Active CIAs



# CIAs by Subject Type





## CIA Requirements

- All CIAs contain the same basic terms.
- Specific provisions and obligations may be tailored to the underlying conduct in the FCA case, the provider type, or to address other concerns by OIG.
  - Billing Fraud
  - Kickbacks or improper referral relationships
  - Medical Necessity
  - Failure of care/provision of worthless or poor-quality services
- OIG is not restricted by the underlying conduct in requiring specific compliance provisions under the CIA



## CIA Term

- CIAs have a 5 year term
- IAs have a 3 year term
- Terms may be extended





## Standard CIA Elements

- Compliance Officer
- Compliance Committee
- Management and Board Obligations
- Written Standards
- Training and Education



## Standard CIA Elements

- Review Procedures
  - Claims Review
  - Arrangements Review
- Screening for Ineligible Persons
- Risk Assessment





## Standard CIA Elements

- Notification of Government Investigations
- Overpayments
- Reportable Events
- Implementation Report/Annual Reports
- Breach and Default Provisions
  - Stipulated Penalties
  - Exclusion for Material Breach



## IRO/Monitor

- Independent Review Organization (“IRO”)
- Selected by provider with approval of OIG
  - Billing Review and Oversight
  - Legal/Financial Arrangements Oversight

- Independent Monitor
- Selected by the OIG, paid by entity
  - Performs Quality Reviews or other Specific Reviews
  - Broad Access, Independent Authority
  - May conduct independent investigations







## Recent Developments

- Board Compliance Obligations
  - Review and Oversight
  - Submit Description of Materials Reviewed
  - Resolution
  - Training
  - Compliance Expert



## Expanded Board Requirements

- “The Board of Directors has made a reasonable inquiry into the operations of [Provider]’s Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [Provider] has implemented an effective Compliance Program to meet Federal health care program requirements and the requirements of this CIA.”





## Management Certifications

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [Provider] policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of [Provider] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”



## CEO Certification

The CEO must certify:

- to the best of his or her knowledge, except as otherwise described in the report, [Provider] has implemented and is in compliance with all of the requirements of this CIA;
- he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- he or she understands that the certification is being provided to and relied upon by the United States.





## Risk Assessment and Internal Review Process

Providers are required to:

- Identify and prioritize risks
- Develop work plans related to identified risks
- Implement work plans
- Ensure that corrective action plans are developed in response to audits
- Track implementation of corrective action plans



## Claims Reviews

- Eliminated discovery sample/full sample and error rate threshold
- Review sample of paid claims for medical necessity, appropriate documentation, coding, and billing
- For any paid claim that results in an overpayment, IRO to review systems and processes and identify problems and weaknesses





## Claims Reviews

- Repayment of identified overpayments
- Evaluate claims review results under CMS overpayment rule to determine if repayment of extrapolated overpayment is required
- Claims review report must provide an estimate of the actual overpayment in the population at the midpoint



## IRO Requirements

- Must assign licensed nurses or physicians with relevant education, training, and specialized expertise to make the medical necessity determinations
- Provider must ensure that IRO has access to all records and personnel necessary to complete the required reviews





## Risk-Based Claims Review

- OIG may limit the population to one or more subsets of paid claims
- Provider or IRO may submit proposals for the subsets of paid claims to be reviewed
- OIG also may select facilities that will be subject to the claims review



## Other Recent Developments

- Provider-Specific Claims Reviews
  - Hospice
  - MDS Review
- Quarterly Claims Reviews in IAs
  - 30 paid claims per quarter
  - Repay identified overpayments and evaluate sample results under 60 day rule
  - IRO must identify actual overpayment in the population at the midpoint





## Other Recent Developments

- Independent Monitor requirements in non-quality of care cases
- First of its kind CIA with electronic health record software developer to assess the quality and safety of the product



## OIG Oversight & Monitoring

- CIAs permit the OIG to have inspection, audit, and review rights.
- Many entities under CIAs have one or multiple onsite visits and inspections by the OIG (routine, non-routine).





## Common Site Visit Inquiries

- Information to validate Compliance Officer's standing and authority within the organization
- Disclosure Log and underlying investigation or review reports
- Dedication of resources to compliance program
- Assessment of compliance "placement" within the organizational structure
- Details of communication between Compliance Officer and Board of Directors
- Compliance Committee Meeting Minutes
- History of development and implementation of corrective action plans



## CIA Enforcement

**CIA's have breach and default provisions.**

**Stipulated Penalties (Monetary Penalties):**

- Failure to use an IRO
- Failure to submit Implementation/Annual Reports
- Failure to identify Unallowable Costs
- Failure to grant the OIG access for investigation
- False Certification
- Failure to adhere to the terms of the applicable CIA





## CIA Enforcement

### **Exclusion for Material Breach:**

- Repeated or Flagrant Violations of the CIA;
- Failure to report a Reportable Event;
- Failure to pay Stipulated Penalties;
- Failure to comply with the Board Expert, IRO, and/or Independent Monitor provisions.



## CIA Enforcement

- CMPL settlements of Reportable Event disclosures
  - Employment of excluded individuals
  - Kickbacks and self-referral violations
  - Improper billing

<https://oig.hhs.gov/fraud/enforcement/cmp/reportable-events.asp>







## Negotiable Terms

- CIAs are standardized and many provisions are non-negotiable, in order to “level the playing field” across entities operating under CIAs.
- CIA provisions may be negotiated to reflect the specific structure and/or operations of an organization.
- Scope of IRO Review in Claims Reviews
- Required certifications “although certifications will be required, the source of the certifications may be negotiable.”
- Opportunities to work with OIG monitor to address any changing or evolving issues throughout the term of the CIA.

